Reviewer’s report

Title: Photobiomodulation therapy on the palliative care of temporomandibular disorder and orofacial/cervical skull pain: study protocol for a randomized, controlled clinical trial

Version: 0 Date: 18 Dec 2018

Reviewer: Daniela Hesse

Reviewer’s report:

Dear authors, thank you for submitting your study protocol for Trials Journals. Whilst the study design of great interest, it has weakness, which are - unfortunately - highlighted by the manuscript.

General Comments:

A comprehensive text revision is advised, including review of the English language, as grammatical and typing mistakes (such as repeated words) appear through the text.

Introduction:

Overall the introduction is well structured, but in my opinion the authors failed in stating the gap in the literature. In the end of the introduction the authors state that "Although there are many studies that report the effects of PBM therapy on TMD, there is still no consensus regarding its effectiveness and which are the best parameters of PBM therapy and which are the locations of the points to be used to apply the laser for the reestablishment of the functions of the stomatognathic system." The problem here is that this study protocol will not test or help establishing the parameters indicated, nor the locations points for laser application. My advice is to review this sentence in order to make clear how your study will contribute in answering questions that are not yet clarified.

Objectives:

The authors state that one of the objectives of this research project is to verify: "If the PBM therapy using low power laser is effective on the palliative care of TMD and orofacial/cervical skull pain." The word "effective" is defined as "adequate to accomplish a purpose; producing the intended or expected result", and therefore can lead to different interpretations. If I understood well, you will verify if the therapy is effective in terms of pain reduction. My suggestion is that you make it more clear.

Methods/ Design:
Study design:

You state that: "The researches, the participants and the statistician will be blinded to the treatments groups (active or placebo)." In this case, who are the researches? Operators? Examiners? How many are they?

Randomization:

Who will be responsible for patients randomization/ allocation to the groups? The operator? One of the evaluators? Someone else not enrolled in the research?

Sample Calculation:

Sample size calculation should be based on your primary outcome analysis. Your sample size was calculated taking a 50% magnitude of effect among the groups; however it is not clear what kind of test you used here or why you choose this effect size. Can you support this based on the literature? Also, why did you not increase the sample size in order to compensate for possible drop-outs?

Outcome measure:

Who will be responsible for the measurements? The examiner (s) will be trained and calibrated? How is this going to be done? Also, for all outcomes measured (such as VAS scale, Sleep quality assessment, quality of life). It is not clear when those outcomes will be measured (only before intervention, before and after?). In the flowchart, as well as in the schedule enrolled there is more information about it, but it should also be better explained in the text. Also, the figure 2 needs to be called in the text.

Statistical analysis:

Statistical analysis needs some more detail. What tests you will apply for each outcomes? Are you planning to perform correlation tests or even build regression models in order to verify the interaction (association/ correlation) of variables that are going to be collected?

Level of interest

Please indicate how interesting you found the manuscript:

An article of importance in its field

Quality of written English

Please indicate the quality of language in the manuscript:
Not suitable for publication unless extensively edited

Quality of figures
All images and figures within the manuscript should be genuine i.e. without evidence of manipulation. No specific feature within an image may be enhanced, obscured, moved, removed, or introduced. If you have concerns about the veracity of the figures you should choose the first option below.

Statistical review
Is it essential that this manuscript is seen by an expert statistician? If so, please give your reasons in your report.

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